510K Summary

FEB 14 2014

Date: Dec 27, 2013

Submitted by: Natus Medical Incorporated
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Propietary Name: Trex_HD

Common Name: Electroencephalograph

Classification Name: Full-montage standard electroencephalograph

Product code: GWQ, OLV

Device Class: II

Predicate Device: Trex (K042150)

Prior Submissions for the same device:

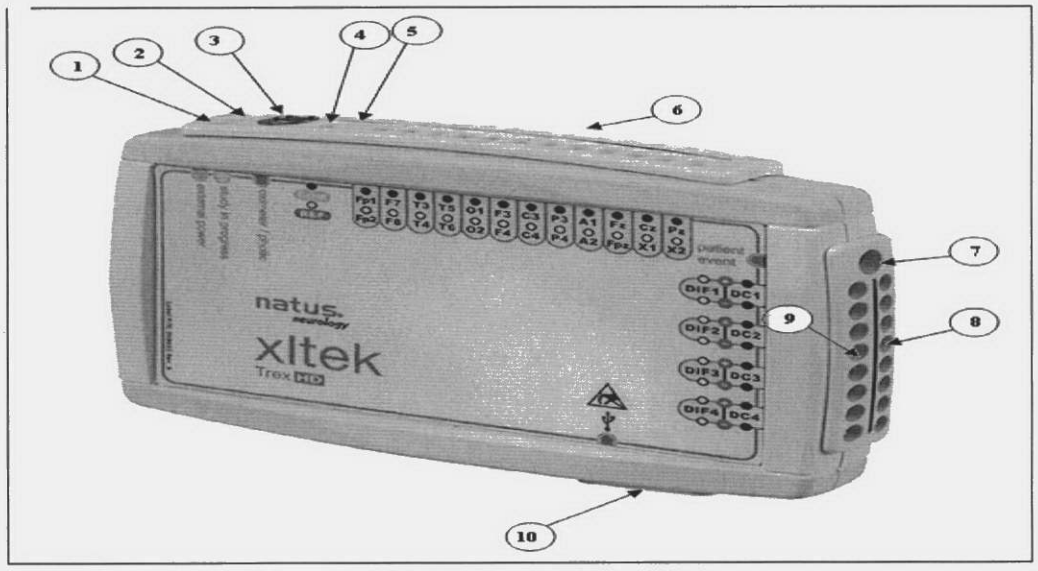
We reference K042150 as the predicate device only. There are no other submissions for the same device as presented here or any other communication from FDA related to it.

Description of the Modified (subject) device

The Trex HD headbox is similar to the cleared Trex headbox (K042150). It contains a complete data acquisition system that has built-in amplifiers, A/D Converters, Digital Signal Processors, and storage devices. Trex_HD, as the predicate device, is composed of

1	24 Referential Inputs	Same as predicate
2	DC Inputs	Same as predicate
3	Differential Inputs	Same as predicate
4	Oximeter / Photic Connection	Same as predicate
5	Patient Event Switch Connection	Same as predicate

6	USB Connection	Same as predicate
7	Video Interface box	New



Trex HD Amplifier

1	Power LED
2	Status LED
3	Oximeter / Photic Connection
4	Reference Input (forward)
5	Common Input (rear)
6	24 Referential Inputs (two rows)
7	Patient Event Switch Connection
8	DC Inputs (rear row)
9	Differential Inputs (forward row)
10	USB Connection (bottom)

Trex HD Video Interface Features

The wireless adapter is a part of Trex HD system. It connects to Camera (Camcorder) via LANC port. It is used to synchronize video frames with the EEG study recorded in Trex HD. It communicates wirelessly with the headbox and can store video synchronization information internally in non-volatile memory in case the wireless communication is not possible.

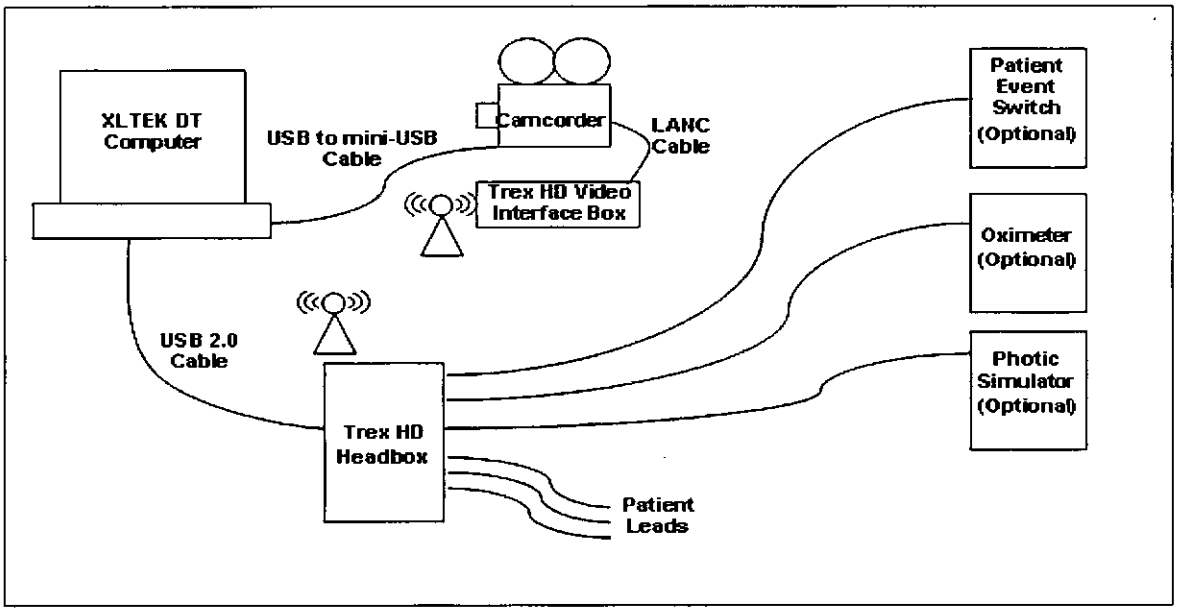
Top view of the Video Interface Box

Bottom view of the Video Interface Box

	Wireless Transceiver - F2M03GLA
Protocol	Bluetooth V2.0 EDR
Operating frequency	2.402 – 2.480 GHz
Transmission power	8dBm
Modulation	GFSK
FCCID	R47F2M03GL

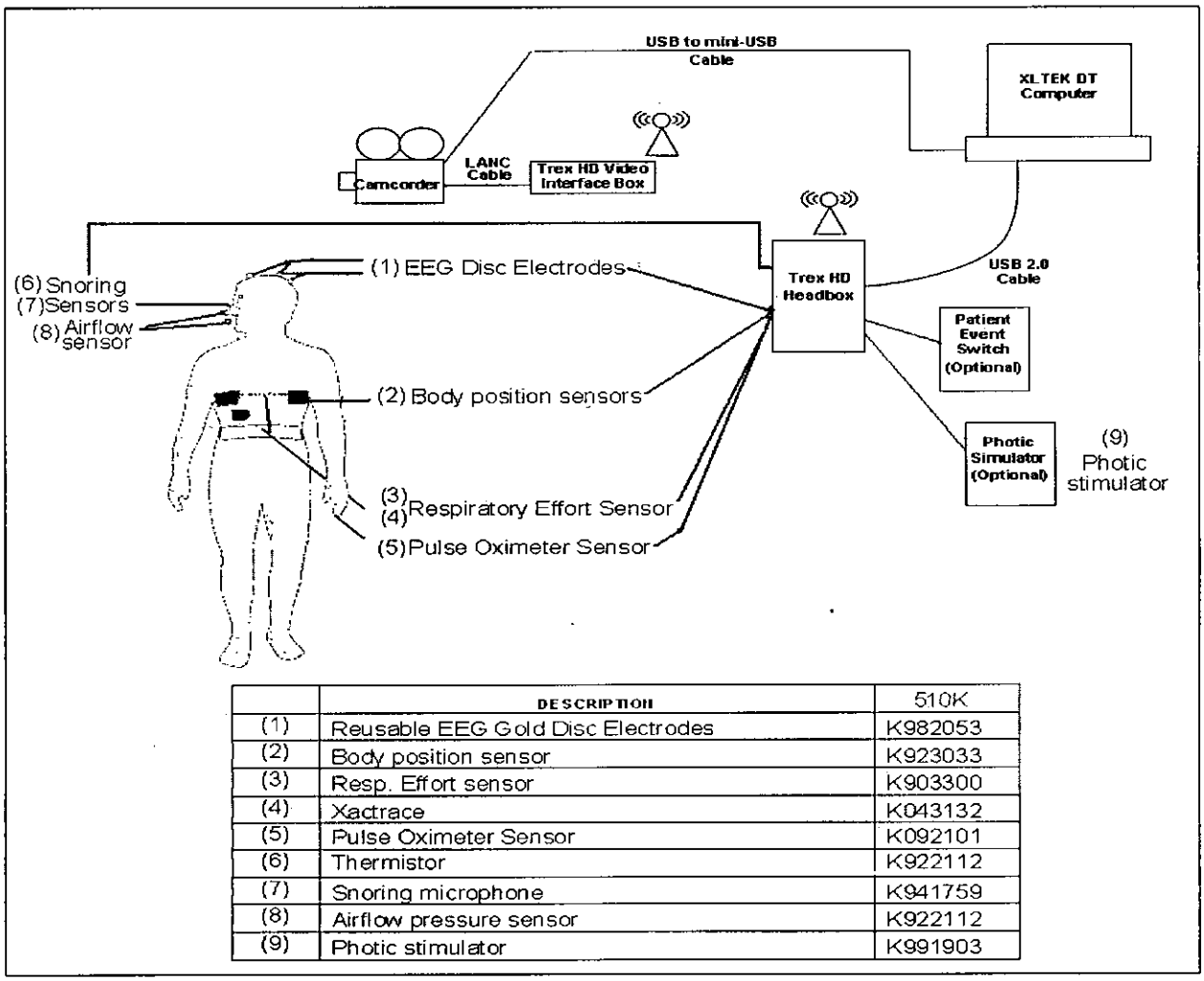
Hardware Set Up

The Trex HD headbox is designed to work with an XLTEK computer system running NeuroWorks (K090019) or SleepWorks software (K090277).
A camcorder can be used to record video. A (Trex HD) Video Interface Box is needed in order to synchronize video recording (on the camcorder) and EEG recording (on the Trex HD headbox).



Device-patient interaction. Accessories List:

The table below lists all accessories to the subject device. Accessories (1) to (8) enter in contact with the patient. Accessories (1) to (8) are to be connected at different regions of the scalp/face and body as illustrated on the image below. These sensors guarantees acquisition of the physiological signals and passively transfer them to the headbox. Characteristics of the sensors vary and are described (cleared) under their respective 510K submissions (see table).



	DESCRIPTION	510K
(1)	Reusable EEG Gold Disc Electrodes	K982053
(2)	Body position sensor	K923033
(3)	Resp. Effort sensor	K903300
(4)	Xactrace	K043132
(5)	Pulse Oximeter Sensor	K092101
(6)	Thermistor	K922112
(7)	Snoring microphone	K941759
(8)	Airflow pressure sensor	K922112
(9)	Photic stimulator	K991903

Indications for Use

The Trex HD is an Electroencephalograph intended to be used to acquire, display, store and archive electroencephalographic signals, intended for electroencephalographic (EEG) or level 1-2 polysomnographic (PSG) recordings. The Trex HD amplifier is designed to be used with Natus NeuroWorks™ or Natus SleepWorks™ software.

Comparison to Predicate Device

	Subject Device Trex HD	Predicate Device Trex (K042150)	Comment
Specification	**Value**		
Indications for Use	The Trex HD is an Electroencephalograph intended to be used to acquire, display, store and archive electroencephalographic signals, intended for electroencephalographic (EEG) or level 1-2 polysomnographic (PSG) recordings. The Trex HD amplifier is designed to be used with Natus NeuroWorks™ or Natus SleepWorks™ software.	The XLTEK TREX is intended to be used as an electroencephalograph: to acquire, digitized, store and archive electroencephalographic signals.	New device IFU includes reference to PSG recordings. These type of recordings, although used for a different purpose compared to EEG only, it is technically similar to multiple parameter EEG recordings. No impact on safety/effectiveness of the device
Technological Characteristics			
	Patient Electrical Connections		
24 Referential Inputs (+ ground, +	+/– 10 mV	+/– 10 mV	Same

	Subject Device Trex HD	Predicate Device Trex (K042150)	Comment
Specification	**Value**		
reference)			
Resolution	16 bit A/D	16 bit A/D	Same
4 Differential Inputs	+/– 10 mV	+/– 10 mV	Same
Resolution	16 bit A/D	16 bit A/D	Same
Common Mode Rejection Ratio	-113 dB @ 60 Hz	-113 dB @ 60 Hz	Same
DC Removal	Infinite	Infinite	Same
Common Mode Input Impedance	> 10 MOhms	> 10 MOhms	Same
Input Noise (peak to peak)	6.4 µV	6.4 µV	Same
Input Noise (RMS)	1.08 µV	1.08 µV	Same
Input Bias Current	< 10 pA	< 10 pA	Same
Channel Crosstalk	56 dB	56 dB	Same
Electrode Connections (including common input)	Safety Touch	Safety Touch	Same
4 Non-Isolated DC Inputs	+/– 5 Volts	+/– 5 Volts	Same
Resolution	16 bit A/D	16 bit A/D	Same
Impedance (kOhm)	<2.5, <5, <10, <25	<2.5, <5, <10, <25	Same
Channel Test Signal	Software selectable	Software selectable	
Sampling Frequency	200 Hz, 256 Hz, 512 Hz	200 Hz, 256 Hz, 512 Hz	Same
	Physical Capabilities		
	Subject Device Trex HD	**Predicate Device Trex (K042150)**	**Comment**
Specification	**Value**		
Oximeter/Photic Stim Connection	Yes (either/or)	Yes (either/or)	Same
Patient Event Button	Yes	Yes	Same
Interface Cable	USB 2.0	USB 2.0	Same
USB Cable Length	Standard Length: 68 inches (~ 147 cm) Maximum Length: 15 feet (4.6 m)	Standard Length: 68 inches (~ 147 cm) Maximum Length: 15 feet (4.6 m)	

	Subject Device Trex HD	Predicate Device Trex (K042150)	Comment
Specification	**Value**		
Main Unit Weight (g)	300	300	Same
Main Unit Size (cm)	10 x 15.5 x 2.5 (h x w x d)	10 x 15.5 x 2.5 (h x w x d)	Same
Batteries	2 AA	2 AA	Same
	Safety		
Leakage Current	<10 µA with 240 VAC on all electrode inputs	<10 µA with 240 VAC on all electrode inputs	Same
	Operating Parameters		
Operating Environmental Limits	Temperature: 10°C to 40°C Humidity 30%–75% Atmospheric Pressure: 700 hP–1060 hP	Temperature: 10°C to 40°C Humidity 30%–75% non-condensing Atmospheric Pressure: 700 hP–1060 hP	Same
Transport and Storage Temperature Range	- 40°C to 70°C	- 40°C to 70°C	Same
Transport and Storage Humidity Range	10–100%, including condensation	10–100%, non-condensing	Same
Transport and Storage Atmospheric Pressure Range	500 hPa–1060 hPa	500 hPa–1060 hPa	Same
	Wireless Transceiver - F2M03GLA		
Protocol	Bluetooth V2.0 EDR	Not Available	
Operating frequency	2.402 – 2.480 GHz	Not Available	
Transmission power	8dBm	Not Available	
Modulation	GFSK	Not Available	
FCCID	R47F2M03GL	Not Available	

The only difference between the subject device and the predicate (K042150) is the addition of the Video Interface box. The Video Interface box is intended to allow time synchronization (via wireless communication) between video images recorded in a separate camcorder and the physiological signals recorded on the Trex_HD headbox.
The wireless communication capability has been added to give flexibility for data acquisition. On the cleared version of the device (K042150) the camcorder could only be connected by cable to the computer imposing restrictions in the video acquisition. Now, with the subject device, the camcorder can be moved around the recording room giving more flexibility for the recording set up. The addition of this part to the subject device has no impact on safety or effectiveness of the subject device compared to the predicate, as demonstrated by the results of extensive testing.

Brief Summary of Performance Tests

Non-clinical:
Testing of the Natus Trex_HD was performed in compliance with Natus Corporation design control process. Testing included:

Test	Results
Trex HD Signal Quality Verification Test	Pass
Trex Functionality Verification Test	Pass
Video Synchronization Verification Test	Pass

The device is in compliance with the following industrial standards

Safety Standard of Compliance and normative references

Standards	Title
CAN/CSA C22.2 No 601.1-M90 UL 60601-1:2003 IEC 60601-1:1988 + A1:1991 + A2:1995 (EN 60601-1:1990 +A1:1992 +A2:1995)	Medical Electrical Equipment Part 1: General Requirements for Safety
CAN/CSA C22.2 No. 60601-2-26-04 IEC 60601-2-26: 2002 (EN 60601-2-26:2003)	Medical Electrical Equipment - Part 2-26: Particular Requirements for the Safety of Electroencephalographs
CAN/CSA C22.2 No. 60601-1-4-02 IEC 60601-1-4: 1996 + A1: 1999 (EN 60601-1-4:2001)	Medical Electrical Equipment - Part 1-4: General Requirements for Safety - Collateral Standard: Programmable Electrical Medical Systems
CAN/CSA C22.2 No. 60601-1-6-05 IEC 60601-1-6: 2004 (EN 60601-1-6:2004)	Medical Electrical Equipment - Part 1-6: General requirements for safety - Collateral Standard: Usability
CAN/CSA C22.2 No. 60601-1-1-02 IEC 60601-1-1: 2000 (EN 60601-1-1:2001)	Medical Electrical Equipment - Part 1-1: General Requirements for Safety - Collateral Standard: Safety Requirements for Medical Electrical Systems

EMC Standard of Compliance and normative references

Standards	Title
IEC 60601-1-2:2001 +A1:2004 / EN 60601-1-2:2001 +A1:2006	Medical Electrical Equipment Part 1-2:General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests

IEC 61000-4-2:2008 / EN 61000-4-2:2009	Electromagnetic Compatibility (EMC) Part 4-2: Testing and Measurement Techniques - Electrostatic Discharge Immunity Test
IEC 61000-4-3:2006 +A1:2007 +A2:2010 / EN 61000-4-3:2006 +A1:2008 +A2:2010	Electromagnetic Compatibility (EMC) Part 4-3: Testing and Measurement Techniques - Radiated, Radio-frequency, Electromagnetic Field Immunity Test
IEC 61000-4-4:2004 +A1:2010 / EN 61000-4-4:2004 +A1:2010	Electromagnetic Compatibility (EMC) Part 4-4: Testing and Measurement Techniques - Electrical Fast Transient/Burst Immunity Test
IEC 61000-4-5:2005 / EN 61000-4-5:2006	Electromagnetic Compatibility (EMC) Part 4-5: Testing and Measurement Techniques - Surge Immunity Test
IEC 61000-4-6:2008 / EN 61000-4-6:2009	Electromagnetic Compatibility (EMC) Part 4-6: Testing and Measurement Techniques - Immunity to Conducted Disturbances, Induced by Radio-frequency Fields
IEC 61000-4-8:2009 / EN 61000-4-8:2010	Electromagnetic Compatibility (EMC) Part 4-8: Testing and Measurement Techniques - Power Frequency Magnetic Field Immunity Test
IEC 61000-4-11:2004 / EN 61000-4-11:2004	Electromagnetic Compatibility (EMC) Part 4-11: Testing and Measurement Techniques - Voltage Dips, Short Interruptions and Voltage Variations Immunity Tests
IEC 61000-3-2:2005 +A1:2008 +A2:2009 / EN 61000-3-2:2006 +A1:2009 +A2:2009	Electromagnetic Compatibility (EMC) Part 3-2: Limits - Limits for Harmonic Current Emissions
IEC 61000-3-3:2008 / EN 61000-3-3:2008	Electromagnetic Compatibility (EMC) Part 3-3: Limits - Limitation of Voltage Changes, Voltage Fluctuations and Flicker in Public Low-voltage Supply Systems
CISPR 11:2009 +A1:2010 / EN 55011:2009 +A1:2010	Industrial, Scientific and Medical (ISM) Radio-Frequency Equipment - Electromagnetic Disturbance Characteristics - Limits and Methods of Measurement

Quality System Compliance:

- ISO 13485:2003 Medical devices - Quality management systems - Requirements for regulatory purposes.
- SOR/98-282 Canadian Medical Device Regulations
- 21 CFR Part 820 US Food and Drug Administration's Quality System Regulation
- 93/42/EEG European Medical Device Directives
- ISO 14971:2007 Medical Devices - Application of Risk Management to Medical Devices
- EN 980:2008 Medical Devices - Symbols for Use of labeling of medical device
- EN 1041:2008 Information supplied by the manufacturer of medical devices
- ISO 15223-1:2012,Medical Devices - Symbols to be Used With Medical Device Labels, Labeling, and Information to be Supplied - Part 1: General requirements
- IEC 62304:2006 Medical device software - Software life-cycle processes

Clinical: Clinical testing was not required to ensure safety and effectiveness of the modified device.

Based on the characteristics of the device as compared to the predicate and the results obtained during verification and other non-clinical testing we conclude that Trex HD is substantially equivalent to the predicate device.

Conclusions

The substantial equivalence of the Natus Trex_HD with Trex amplifier was demonstrated by testing in compliance with the Design Control process. The intended use and technology of the Trex_HD is similar to that of the predicate device XLTEK-Trex. Validation was performed to ensure no new questions of safety or effectiveness are raised.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 14, 2014

Natus Medical Incorporated
DBA Excel-Tech Ltd. (XLTEK)
c/o Mr. Daniel Ramirez
2568 Bristol Circle
Oakville, Ontario
Canada L6H 5S1

Re: K131266
Trade/Device Name: Trex HD
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: GWQ
Additional Product Code: OLV
Dated: January 14, 2014
Received: January 17, 2014

Dear Mr. Ramirez:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Joyce M. Whang -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K131266

Device Name
Trex HD

Indications for Use *(Describe)*
The Trex HD is an Electroencephalograph intended to be used to acquire, display, store and archive electroencephalographic signals, intended for electroencephalographic (EEG) or level 1-2 polysomnographic (PSG) recordings. The Trex HD amplifier is designed to be used with Natus NeuroWorksTM or Natus SleepWorksTM software.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Joyce M. Whang -S

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